Venn Life Sciences

part of hVIVO

Case study | Non-clinical consultancy

Introduction

A small sized pharmaceutical company, who had already performed proof-of-concept studies with a small molecule drug candidate came to Venn Life Sciences with the aim to bring their product into clinic as soon as possible.

Challenges

The company's first objective was to run a clinical study as soon as possible; however they did not have the knowledge or expertise on what requirements were needed in terms of safety information for a phase I clinical trial. Their second objective was to have support in all regulatory documentation (IND modules, IB), which needed to be written prior to the study & needed to be accurate, to avoid any delays to their clinical study.

Solution

This client required the expertise and attention of the Venn Life Sciences team, consisting of CMC, non-clinical and clinical consultants. As a first step, a Drug Development Plan (DDP) was written for which experts of all teams contributed. The DDP provided a plan for all the requirements needed in order to start the clinical study, including an estimation of costs and timelines.

The Venn non-clinical team selected CRO's in accordance with the wishes of the client and the Venn consultants acted as the main point of contact for the study. As main point of contact, the Venn experts were in close contact with the CRO's and with the client's contact person. The team discussed the study design, monitored the progress of all studies, and reviewed the reports.

The final step of the process entailed the Venn team compiling all non-clinical information into an Investigators Brochure, and into the non-clinical modules of IND.

Results

The documents prepared by the Venn Life Sciences team formed the core of the CTA / IND application of the phase 1 trial